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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,293	03/04/2002	E. Marlowe Goble	MED-3	6561

7590

10/14/2003

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Waltham, MA 02154

EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 10/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

**Office Action Summary**

Application No.

10/090,293

Applicant(s)

GOBLE ET AL.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 05.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13,14,35-64 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claims 13,14, lines 11,12, claims 35, 38, 41, 44,46, 49, 52,55, lines 4-14, claims 57,61, lines 2-11, applicant positively recites part of a human, i.e. "wherein the first vertebra" and "a natural vertebral body" respectively. Thus, claims 13,14, 35-64 includes part of a human body within their scope and are therefore, non-statutory.

A claim directed to or including within its scope part of a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 11, line 1, the term "said flange" lacks prior antecedent basis.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley (6,610,091) in view of Ray et al (6,113,639).

With respect to claims 1,9,13,14,17,30,31,33,34,35,38,41,44,46,49,52,55,Reiley discloses a prosthesis (330,500,700) comprising a surface (315) that articulates with another facet surface and a fixation portion (310) the surface being connected to the fixation portion; the prosthesis cooperates with a natural disc so as to restore the natural biomechanics of a spinal motion segment.

It is noted that Reiley did not teach of an artificial disc as claimed by applicant. However, in a similar art, Ray et al evidence the use of an artificial disc and a kit to replace the function of a degenerated disc and to avoid placing unnecessary and possibly destructive forces on an already damaged annulus.

Therefore, given the teaching of Ray et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the disc of Reiley with the artificial disc of Ray et al to replace the function of a degenerated disc and to avoid placing unnecessary and possibly destructive forces on an already damaged annulus.

With respect to claims 2-8,10-12,18-26,36,37,39,40,42, 43,45,47,48, 50,51,53, 54 56; the above combinations of references teaches all the limitations, as set forth.

With respect to claims 27-29,57-64, the method steps, as set forth, would have been obviously carried out in the operation of the device, as set forth above.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,571,191	11-1996	Fitz
5,527,312	06-1996	Ray
6,132,464	10-2000	Martin
6,419,703	07-2002	Fallin et al.
6,579,319	06-2003	Goble et al.
6,565,605	05-2003	Goble et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene  
September 08, 2003

  
PEDRO PHILOGENE  
PRIMARY EXAMINER